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International application number: PCT/US05/001070

International filing date: 12 January 2005 (12.01.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/551,170
Filing date: 08 March 2004 (08.03.2004)

Date of receipt at the International Bureau: 03 March 2005 (03.03.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

1286839

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APPLICATION NUMBER: *60/551,170*
FILING DATE: *March 08, 2004*
RELATED PCT APPLICATION NUMBER: *PCT/US05/01070*

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13146 U.S.PTO 030804

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. EV343594741US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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☐ *Additional inventors are being named on the ______ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

INSTRUMENTS HAVING WIRELESS LOCALIZATION TRANSPONDERS FOR PERFORMING MEDICAL PROCEDURES

CORRESPONDENCE ADDRESS
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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 12 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 7 ☒ Other (specify): Postcard, Check No. 5011 ($80)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.
☒ A check or money order is enclosed to cover the filing fees
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$80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☒ No. .
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____.

Respectfully submitted,
SIGNATURE [signature]

Date March 8, 2004

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EXPRESS MAIL CERTIFICATE:

I hereby certify that this communication is being deposited with the United States Postal Service via Express Mail No. EV343594741US under 37 C.F.R. § 1.10 on the date indicated below addressed to: Mail Stop Provisional Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

March 8, 2004
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INSTRUMENTS HAVING WIRELESS LOCALIZATION TRANSPONDERS FOR PERFORMING MEDICAL PROCEDURES

APPLICATION(S) INCORPORATED BY REFERENCE

[0001] The present application claims the benefit of U.S. Application No. 60/536,008, filed on January 12, 2004, entitled "INSTRUMENTS HAVING WIRELESS LOCALIZATION TRANSPONDERS FOR PERFORMING MEDICAL PROCEDURES," which is incorporated herein, along with Appendices A-F filed therewith, by reference in their entirety. The following pending patent applications identified by U.S. Application Nos. are also incorporated herein by reference in their entirety: 10/416,827; 09/954,700; 10/213,950; 10/679,801; 10/382,123; 10/334,658; 10/746,888; and 10/749,478.

TECHNICAL FIELD

[0002] The present application is related to catheters, electrodes and other instruments used for surgical applications (e.g., minimally invasive), neurostimulation, cardiac electrophysiology, and other applications.

BACKGROUND

[0003] Many medical procedures involve locating an electrode, scalpel or other instrument within a patient. For example, electrodes for cardiac defibrillation and/or pacing are positioned in and/or near the heart to deliver electrical stimulation along selected vectors, or electrodes for neurostimulation can be implanted near the spine for treating pain or in deep brain locations for treating epilepsy, movement disorders and other disorders. Other procedures, such as

minimally invasive surgeries, position a scalpel, ablation tip or other device proximate to the treatment area within the patient. In many of these applications, it is important to determine and track the location of the tip of the catheter for accurately locating the therapy device at the internal treatment area in the patient.

[0004] Cardiac pacing and/or defibrillation is a common procedure in which a pulse generator, electrical leads and electrodes are implanted within a patient. A typical pulse generator includes a power supply, capacitor(s), and a control system for delivering electrical pulses to the electrodes. The electrodes are generally implanted in one or more chambers of the heart, and the leads electrically couple the electrodes to the pulse generator.

[0005] A conventional system for implanting stimulation electrodes used in cardiac pacing and/or defibrillation involves implanting the leads using a catheter inserted into the femoral artery. The vascular pathway for the catheter and the location of the catheter are determined periodically using fluoroscopy techniques in which a radio-opaque dye is injected into the patient to identify the pathway and the patient is repeatedly irradiated. Although fluoroscopy is a well known procedure, it exposes the patient and practitioners to a significant amount of radiation. Therefore, it would be desirable to develop a system for locating an electrode that mitigates radiation exposure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 is a partial cross-sectional view of an instrument having a wireless localization transponder.

[0007] Figure 2 is a schematic view of the distal end of the instrument shown in Figure 1 in use in a cardiac application.

[0008] Figure 3 is a side view of an electrode for deep brain stimulation.

[0009] Figure 4 is a cross-sectional view schematically illustrating an implantable electrode with a wireless localization transponder in accordance with an embodiment of the invention.

[0010] Figure 5 is a flow-chart of a method for implanting an electrode in accordance with an embodiment of the invention.

[0011] Figure 6 is a cross-sectional view of an intravascular electrode implantation in accordance with the invention.

[0012] Figure 7 is a cross-sectional view of illustrating an aspect of a method in accordance with the invention.

DETAILED DESCRIPTION

[0013] Figure 1 is a partial cross-sectional view of an instrument 10 for performing a minimally invasive surgery, electrode implantation/extraction, or other minimally invasive procedures. The embodiment of the instrument 10 shown in Figure 1 includes a handle 12 and a flexible member 14 extending from the handle. The flexible member 14 can be a catheter having a lumen or a solid body. The flexible member 14 is configured to be inserted into the patient and to travel within the vasculature, throat, respiratory passageways, intestinal tracts or other parts of the patient. The flexible member 14, for example, can be configured to be inserted into the vasculature through an incision, and then moved through the vasculature to position the distal portion of the flexible member 14 at a desired treatment site within the patient.

[0014] The instrument 10 also includes an operative element 18 carried by the flexible tube. The operative element 18 can be a scalpel, stimulation electrode, sensor, ablation electrode, optical member (e.g., optical fiber/light source), radiation source, or other feature for performing a procedure. The operative element 18 can be coupled to an energy source, fluid system or other device by a line 19 extending at least partially through the flexible member 14. The line 19, for example, can be an electrical lead when the operative element 18 is an electrode contact to transmit electrical current to/from the electrode contact. The operative element 18 is generally located at a distal region of the flexible body 14 relative to the handle 12.

[0015] The instrument 10 also includes a wireless marker 20 that wirelessly transmits a localization signal in response to a wirelessly transmitted excitation energy. The wireless marker 20, for example, can be a small magnetic resonator that produces an alternating magnetic field in response to an alternating excitation field. Suitable magnetic transponders and the systems for producing the excitation fields, processing the signals from the transponders, and computing the location of the transponder are described U.S. Application Nos. 10/416,827; 09/954,700; 10/213,950; 10/679,801; 10/382,123; 10/334,658; 10/746,888; and 10/749,478 incorporated by reference above. The wireless marker 20 can be identical to any of the markers disclosed in these co-pending applications, but it does not necessarily need to be encapsulated in a separate capsule or housing. For example, the wireless marker 20 can include a core 22, a coil 24 and a capacitor 26 electrically coupled to the coil 24 without a separate capsule. The marker 20 can accordingly be embedded in the flexible member 14 or a separate electrode without additional encapsulation. Alternatively, the marker 20 can also be encapsulated in a separate capsule as shown in U. When the marker 20 is encapsulated in a separated capsule, it can be attached to an external portion of the flexible member 14 or embedded in the flexible member 14.

[0016] Figure 2 illustrates on example of using the instrument 10 for cardiac electrotherapy, such as cardiac monitoring, ablation, pacing and/or defibrillation. In this embodiment, the flexible member 14 is inserted into the femoral artery and guided to the inferior vena cava using the localization signal from the marker 20 and/or other guidance techniques (e.g., guide wire). From the inferior vena cava, the operative element 18 at the distal tip of the flexible member 14 is located in or proximate to a desired location of the heart for the specific treatment. The instrument 10 can be inserted into other vessels for placing the operative element at difference locations in or proximate to the heart or other body part in a similar manner.

[0017] Figure 3 illustrates a different embodiment of an electrode 100 for deep brain stimulation. In this embodiment, the electrode 100 has a shaft 110, a

plurality of electrode contacts 112a-c, and a lead wire electrically coupled to the electrode contacts 112a-c. The electrode 100 can alternatively have only a single electrode contact. The shaft 110 is generally rigid, but it can be flexible in certain embodiments.

[0018] The electrode 100 also includes a wireless marker 20. In this embodiment, the wireless marker 20 is carried at the distal end of the shaft 110, but it can be located at a different region of the shaft 110. The location of the electrode contacts 112a-c can be determined relative to an internal stimulation site within the brain be computing the location of the marker 20 as set forth in Appendices A-F. As such, the electrode contacts 112a-c can be accurately positioned within the brain proximate to the neurons that are to be stimulated. In one embodiment, the marker 20 guides the electrode 110 to position the electrode contacts 112a-c proximate to the vagus nerve, but it will be appreciated that the electrode 100 can be configured for use in many other applications to stimulate other nerves.

[0019] Figure 4 is a cross-sectional view schematically illustrating an implantable electrode 400 defining another embodiment of the operative element 18 described above. The electrode 400 can be implanted intravascularly in a vessel or the heart for use with implantable pacing and/or defibrillation devices. As such, the electrode can be positioned within a lumen 16 of the flexible member 14 for delivery to the heart or another location.

[0020] In this embodiment, the electrode 400 includes a body 410 generally composed of a dielectric material, an electrical contact 412, and a lead 414 attached to the contact 412. The lead 414 can be attached to a pulse generator for carrying electrical pulses and/or signals to or from the contact 412. The contact 412 is accordingly electrically conductive to deliver electrical pulses to the patient or act as a sensor. The electrode 400 also includes an anchor 418 (shown schematically) that can secure the electrode to tissue upon deployment. The anchor 418 can be a stent, barb or other device known in the art for holding an electrode within a chamber of the heart or a vessel.

[0021] The electrode 400 further includes one or more wireless markers 20 carried by the body 410. The wireless marker 20 can be enclosed by the body 410 or attached to an external surface of the body 410. The wireless marker 20 can be a magnetic resonator in accordance with any of the embodiments set forth in the foregoing applications incorporated by reference.

[0022] The electrode 400 can be attached to an actuator 430 via a coupling 432. The actuator 430 generally extends through the lumen 16 or otherwise along the flexible member 14 between the coupling 432 and the handle 12 at the proximate end of the flexible member 14. The actuator 430 operates the coupling 432 to deploy the electrode 400 at a desired location for implantation.

[0023] Figure 5 is a flow-chart illustrating a method 500 for implanting an electrode in accordance with an embodiment of the invention. The method 500 can include a first stage 502 for determining a pathway for implanting the electrode 400. The first stage 502, for example, can include injecting a radio-opaque dye into the patient and using fluoroscopy to identify a vascular pathway through which the flexible member 14 can pass to the patient's heart or another location. The method 500 also includes a second stage 503 involving inserting the flexible member 14 with the electrode 400 or another operative element 18 into the patient and moving the flexible member 14 through the pathway. In several applications, the flexible member 14 can be inserted into the femoral vein and guided to the heart.

[0024] The method 500 also includes a third stage 504 comprising tracking the position of the electrode 400 along the pathway within the patient using the wireless marker 20 or another non-ionizing marker that generates or otherwise emits a signal. In one embodiment, the position of the electrode is determined by generating an alternating magnetic field that excites the marker 20, and then detecting a response magnetic field from the marker 20. As set forth in the applications incorporated by reference herein, the three-dimensional location of the marker 20 can be determined in real-time. More specifically, the location of the marker 20 can be determined at a frequency of 1Hz – 60Hz, and the latency

from the time the measurement is taken until the location is determined is approximately 10ms – 500ms. These ranges are just an example of the ability to track the location of the electrode 400 or another operative element 18 during insertion to provide location data at a sufficiently high frequency within a short period after taking the measurements.

[0025] The third stage 504 of the method 500 can optionally include periodically updating the location of the electrode 400 based upon the determined location of the marker 20 using fluoroscopy. The fluoroscopic image can be used to confirm the determined location of the marker 20 based on the signal from the marker.

[0026] The method 500 can further include an optional fourth stage 505 comprising attaching the electrode 400 to the patient. The electrode 400 can be attached to a chamber in the heart or a vessel, such as left ventricle, right ventricle, left atrium or right atrium. In many applications, more than one electrode is implanted in the patient such that electrodes can be implanted within the left ventricle, right ventricle, left atrium, right atrium, coronary sinus, inferior vena cava, superior vena cava and/or other vessels to provided the correct vectoring of the electrical pulses across the heart to achieve the desired result.

[0027] The method 500 can further include electrically stimulating the patient to pace and/or defibrillate the heart. In general, pacing involves stimulating the heart a regular intervals using a relatively low energy level, and defibrillation involves stimulating the heart upon detection of fibrillation or other parameters at a much higher energy level.

[0028] Figure 6 is a schematic view of an implantable stimulation system for pacing and/or defibrillating the heart. In this embodiment, the system includes a first electrode 400a implanted in the right atrium and a second electrode 400b implanted in the right ventricle. The first electrode has a first lead 414a, and the second electrode 400b has a second lead 414b. The first and second electrodes 400a and 400b can be similar to the electrode 400 described above, and these electrodes can be implanted using the method 500 described above. The system further includes an implanted pulse generator 600 to which the leads 414a and

414b are electrically coupled. The pulse generator 600 can further include an external electrical contact 602 to provide another location for creating a vectors along which electrical pulses can be directed.

[0029] Figure 7 is a schematic view illustrating a plurality of electrodes 400 attached to the heart for use in another embodiment in accordance with the invention. In this embodiment, an electrode is attached to the heart in the right atrium, right ventricle and the left ventricle. The electrodes 400 are left in the heart, and the relative distance between the electrodes is monitored. The change in relative distances between the electrodes may provide in indication of a condition of the heart. For example, the distances D_1-D_3 shown in Figure 7 may change over time after pacing the heart using electrical stimulation. It will be appreciated that the markers 20 can be implanted into the heart without being part of an electrode in an alternative embodiment of this method.

[0030] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the invention. For example, instead of implanting electrodes in the method 500, stents or other devices that are commonly implanted using fluoroscopically guided catheters can guided with the markers 20. Accordingly, the invention is not limited except as by the appended claims.

CLAIMS

I/We claim:

[c1] 1. An instrument for performing an invasive procedure in a patient, comprising:

a body configured to pass through an internal portion of the patient;

an electrode contact on the body;

a lead extending along the body and coupled to the electrode contact; and

a wireless marker carried by the body, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame.

[c2] 2. The instrument of claim 1 wherein the body is a flexible member configured to pass through vasculature of the patient.

[c3] 3. The instrument of claim 1 wherein the body is a flexible member configured to pass through at least a portion of the patient.

[c4] 4. The instrument of claim 1 wherein the body is a shaft configured to be inserted into the patient.

[c5] 5. The instrument of claim 4 wherein the shaft is rigid.

[c6] 6. The instrument of claim 4 wherein the shaft is rigid and configured to be implanted in the brain of the patient.

[c7] 7. The instrument of claim 1 further comprising a plurality of electrode contacts on the body, wherein the lead has a plurality of electrode wires individually attached to different electrode contacts.

[c8] 8. An instrument for performing a minimally invasive procedure in a patient, comprising:

a flexible member configured to pass through an internal portion of the patient;

an operative element carried by the flexible member; and

a wireless marker carried by the flexible member, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame.

[c9] 9. The instrument of claim 8 wherein the flexible member is a catheter.

[c10] 10. The instrument of claim 9 wherein the operative element is at least one of an electrode contact, a sensor, a scalpel, an ultrasound emitter and/or a radiation source.

[c11] 11. An implantable electrode, comprising:

a body;

an electrical contact carried by the body, the electrical contact being composed of an electrically conductive material; and

a wireless marker carried by the body, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame.

[c12] 12. The implantable electrode of claim 11, further comprising an anchor to hold the electrode to tissue within the patient.

[c13] 13. The implantable electrode of claim 11, further comprising a lead electrically coupled to the contact.

[c14] 14. A system for providing electrical stimulation to a patient, comprising:

a pulse generator configured to be implanted in a patient;

an implantable electrode having (a) a body, (b) an electrical contact carried by the body, the electrical contact being composed of an electrically conductive material, (c) and a wireless marker carried by the body, the wireless marker having a transponder that produces a wirelessly transmitted signal in response to a wirelessly transmitted excitation energy for determining the position of the marker in a reference frame; and

a lead electrically coupling the pulse generator to the contact.

[c15] 15. A method of implanting an electrode, comprising:

inserting a flexible member having a deployable electrode into a vascular pathway of a patient;

tracking the position of the electrode within the vascular pathway by (a) wirelessly transmitting an excitation energy to a marker carried by the electrode, (b) wirelessly transmitting a response signal from the marker, wherein the response signal includes data indicative of the location of the marker in a reference frame, and (c) calculating the location of the marker based on the response signal.

[c16] 16. The method of claim 15 wherein the marker includes a magnetic transponder, the excitation energy is an alternating magnetic field, and the response signal is a corresponding alternating magnetic field.

[c17] 17. The method of claim 16, further comprising periodically imaging the electrode within the vascular pathway using fluoroscopy.

[c18] 18. The method of claim 17, further comprising attaching the electrode to the right atrium, left atrium, left ventricle, right ventricle, inferior vena cava, superior vena cava, and/or coronary sinus.

[c19] 19. A method of ascertaining a heart condition, comprising:

implanting a plurality of wireless markers in a heart of a patient; and

determining changes in relative distance between the markers by (a) wirelessly transmitting a distinct alternating magnetic field to each marker, (b) wirelessly transmitting a distinct response signal from each marker, wherein the response signals include data indicative of the location of each marker in a reference frame, and (c) calculating the location of each marker based on the response signal.

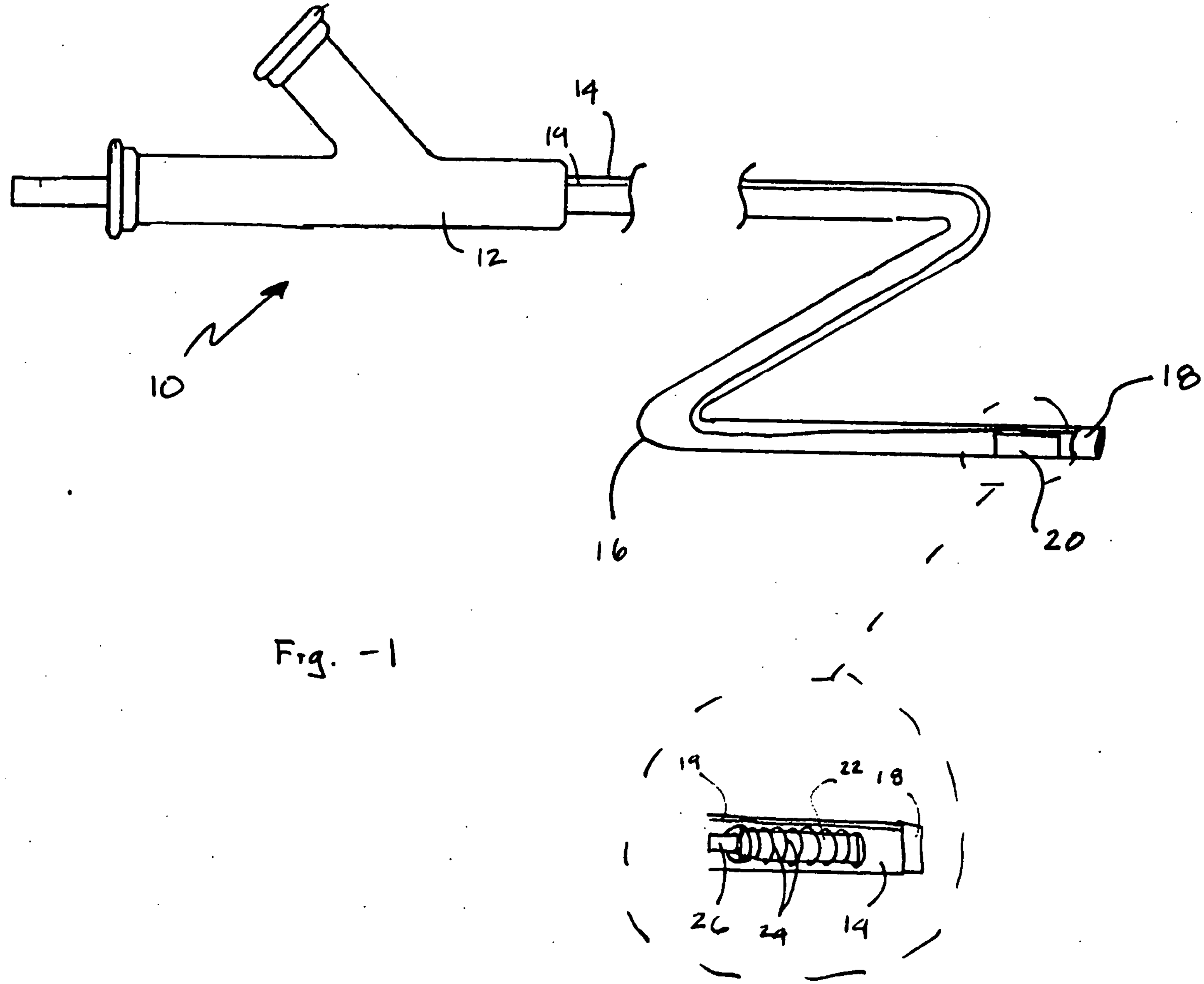
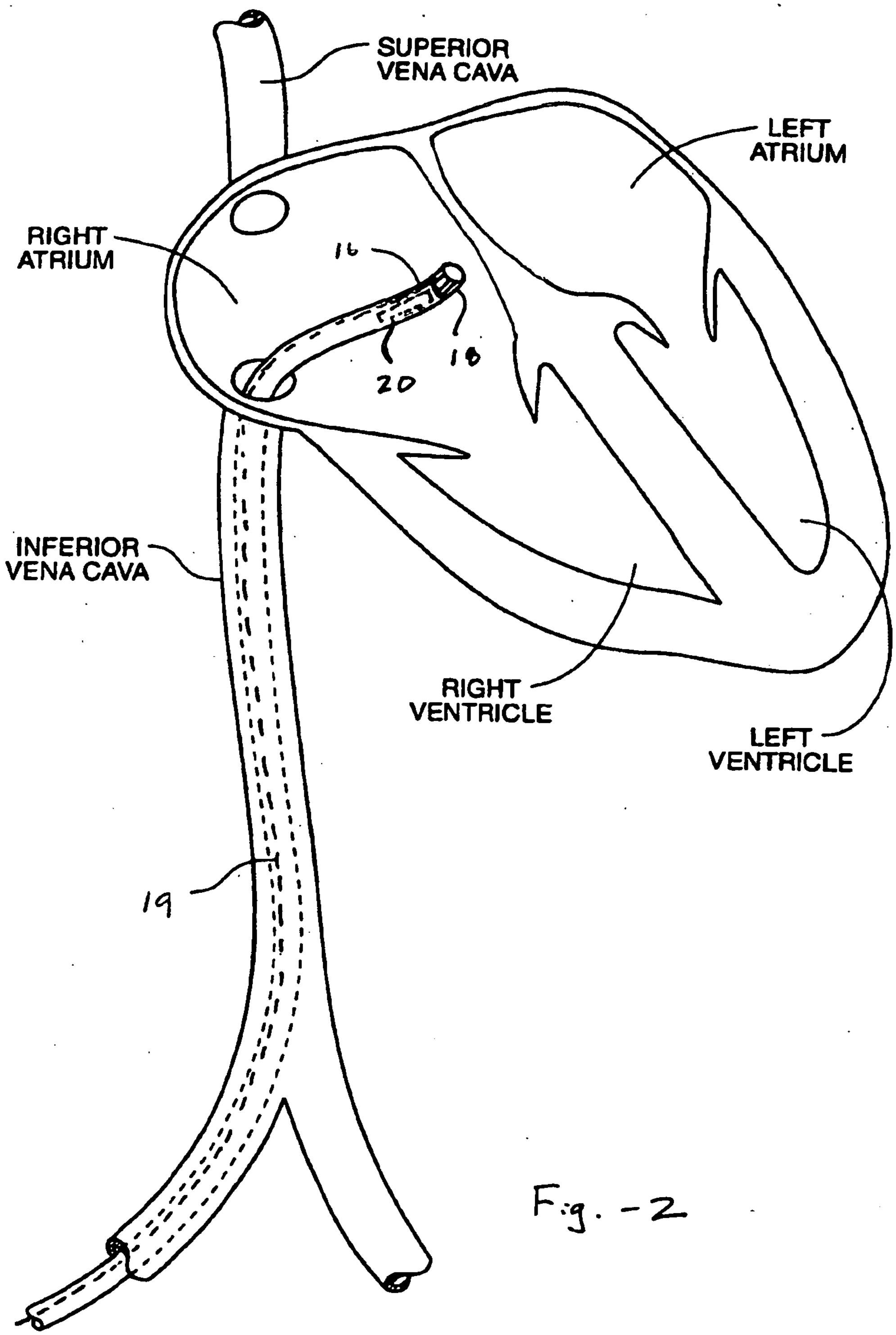


Fig. -1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VENA CAVA
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16
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19

Fig. -2

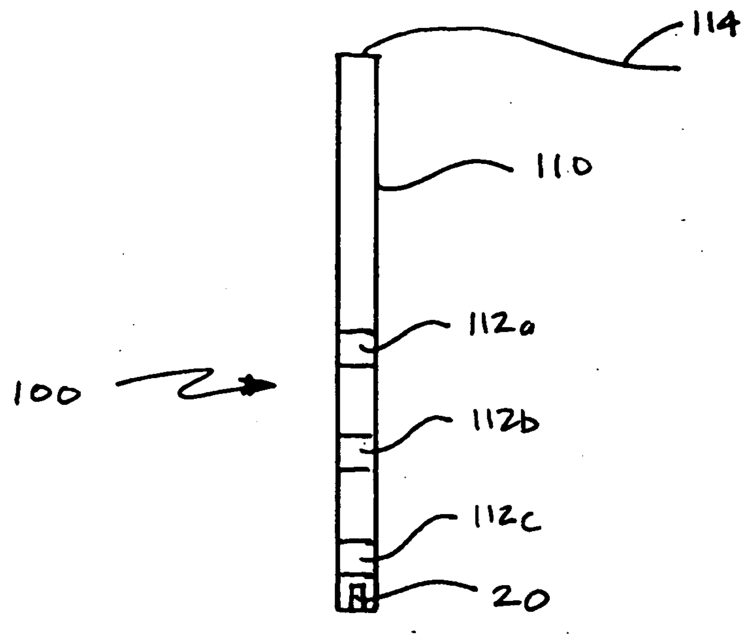


Fig. -3

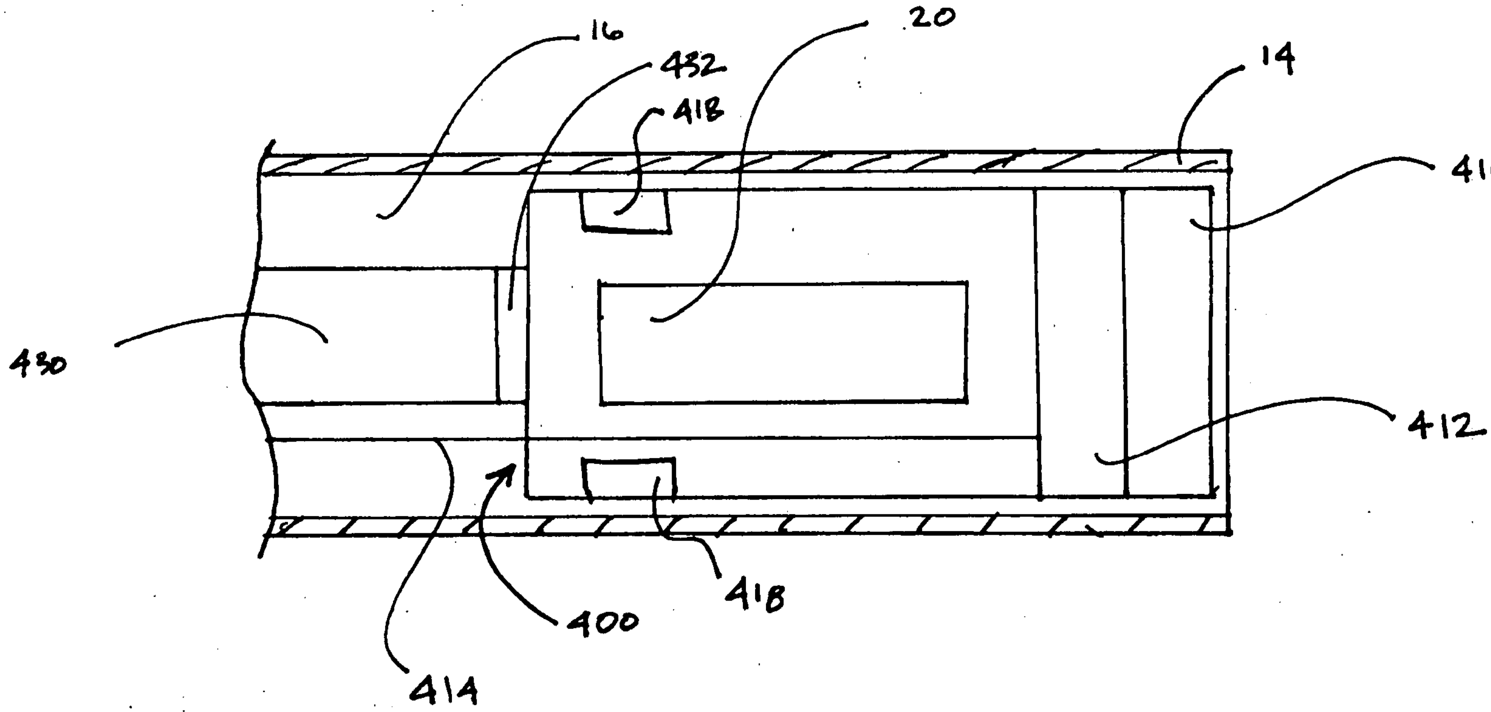
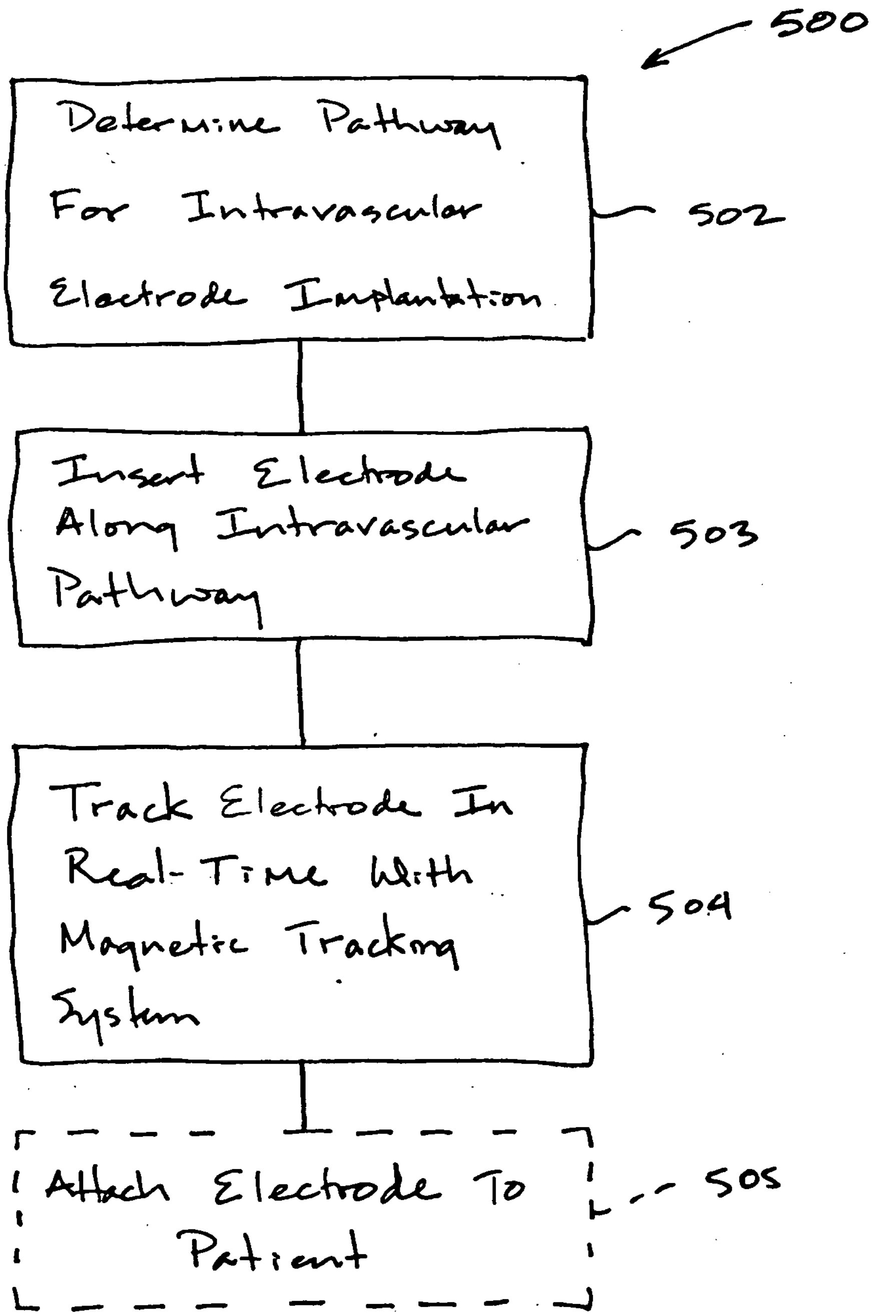


Fig- 4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Determine Pathway For Intravascular Electrode Implantation
502
Insert Electrode Along Intravascular Pathway
503
Track Electrode In Real-Time With Magnetic Tracking System
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Attach Electrode To Patient
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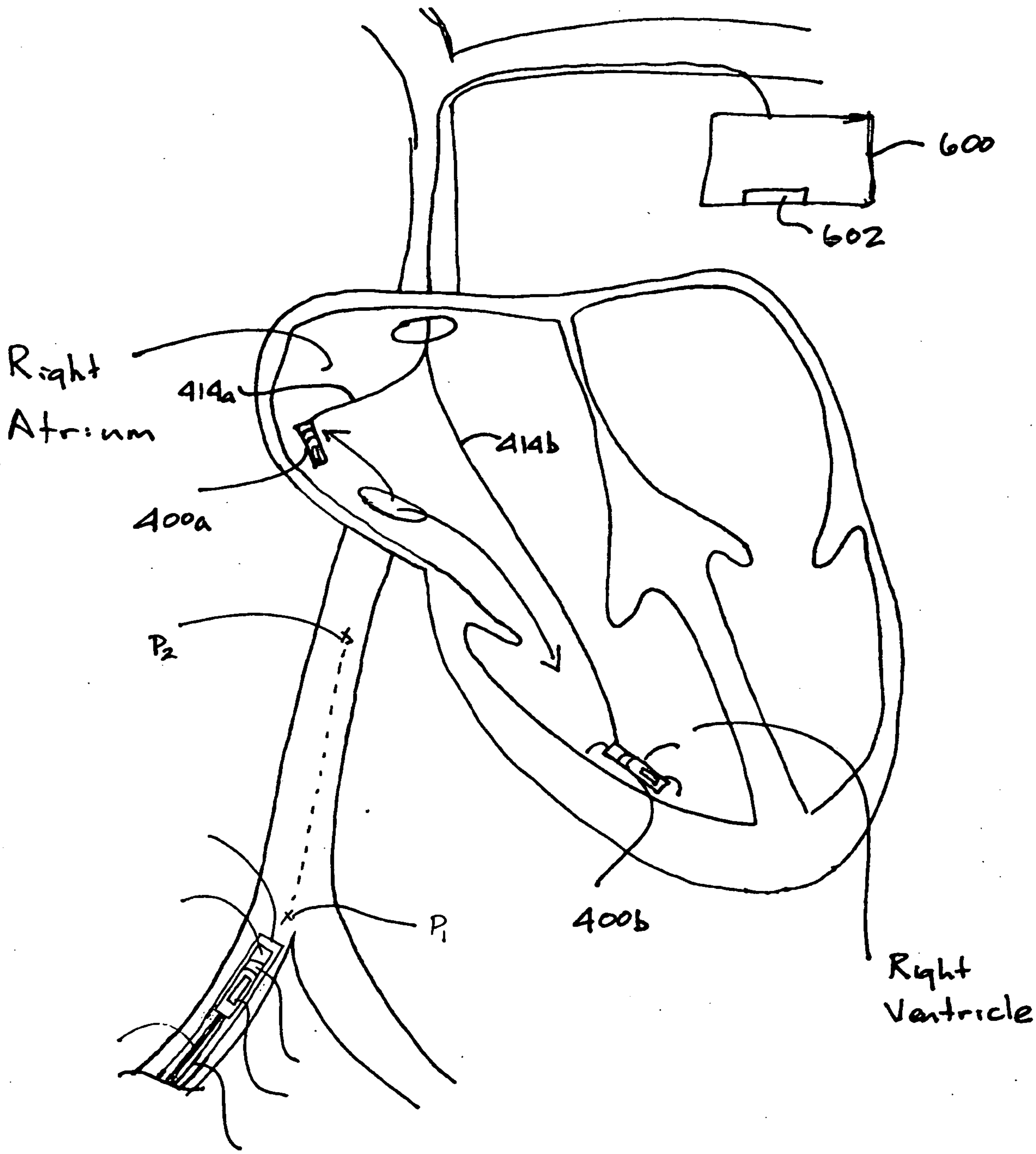
Fig. - 5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P2
P1
400b
Right
Ventricle

Fig. – 6

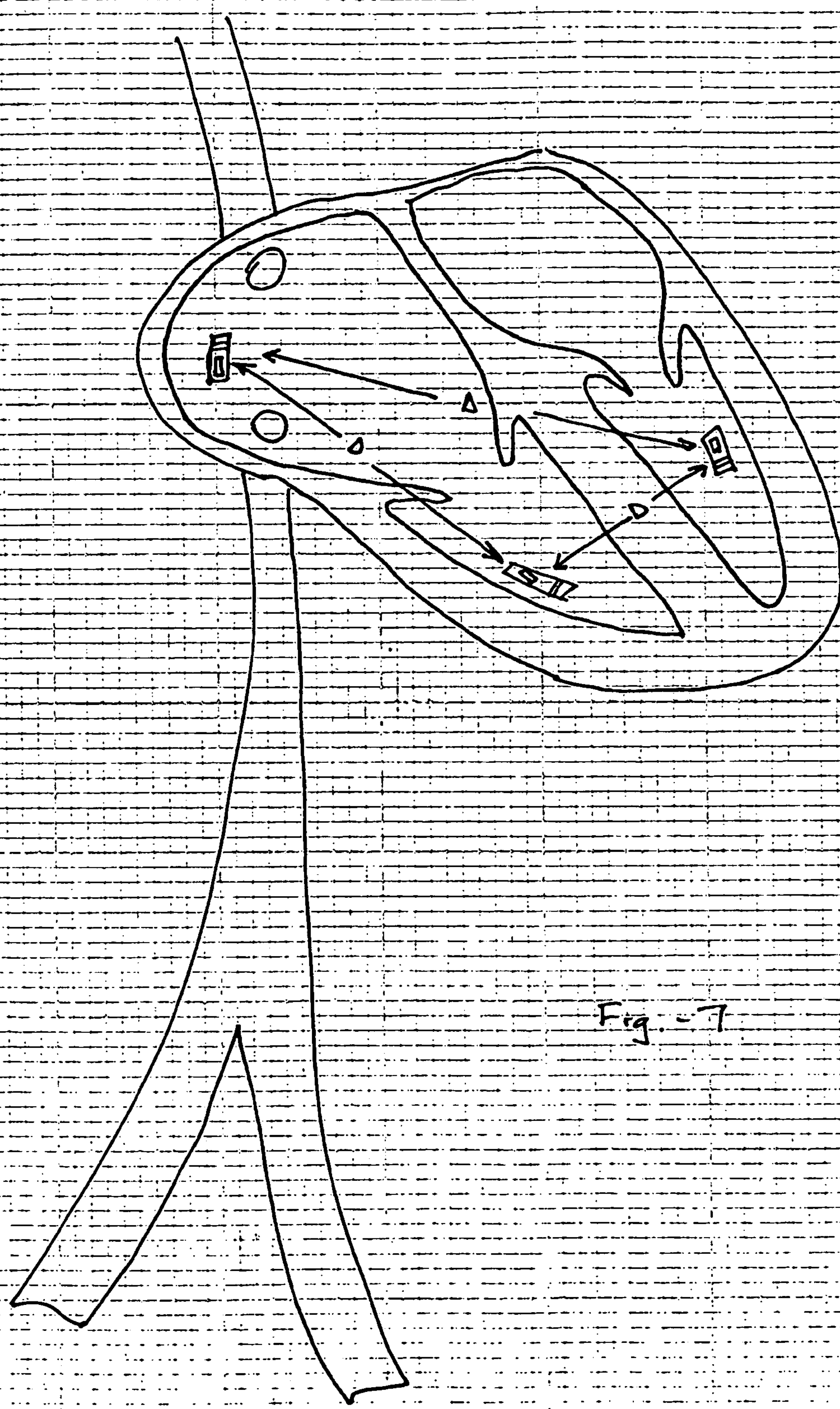

Fig. - 7